

Notice of Allowability

Application No.

09/762,302

Examiner

Humera N. Sheikh

Applicant(s)

DIETRICH ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 28 November 2005.
2. ☒ The allowed claim(s) is/are 21-42 and 44-57.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

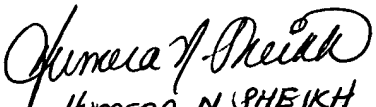
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____


HUMERA N. SHEIKH
PATENT EXAMINER
TC-1600

DETAILED ACTION

Status of the Application

Receipt of the Response to Non-Final Office Action, the Amendment and Applicant's Arguments/Remarks, all filed 11/28/05 is acknowledged.

Claims 21-42 and 44-57 are pending in this action. Claims 21 and 26 have been amended. New claims 44-57 have been added. Claims 1-20 and 43 have been cancelled. Claims 21-42 and 44-57 are allowed.

EXAMINER'S AMENDMENT

The application has been amended as follows:

In the Specification:

On page 1, beginning on the first line after the title of the invention, the phrase **"This application is a 371 of PCT/EP99/05724 filed August 07, 1999 and claims priority to EPO Application No. 98115141.8 filed August 12, 1998"** has been added.

In the Claims:

In claim 25, the term 'Crosopovidone' has been changed to "crospovidone".

In claim 39, the term 'select' has been changed to "selected".

In claim 44, the term 'membranes' has been changed to "membrane".

Allowable Subject Matter

Claims 21-42 and 44-57 are allowed.

The following is an examiner's statement of reasons for allowance:

The primary reasons for allowance are that the prior art (Dietrich *et al.* – WO 97/02020 & Chen – U.S. Patent No. 5,260,069) does not disclose nor fairly teach or suggest the instant active compound, which is pyridine-2-ylmethylsulfinyl-1H-benzimidazole, in an oral fixed combination administration form, provided in a capsule in two discrete and separate dosage administration forms, separately bearing either an enteric coating or a sustained-release coating. More specifically, the prior art does not disclose nor teach a sustained release coating film that is a water-insoluble and physiologically tolerable plastic membrane having low swelling power in water and in which small soluble particles are embedded. The instant oral administration form also provides a distinction between the instant sustained-release coating film and the instant enteric coating film since the instant sustained release coating film includes the presence of small soluble particles embedded therein. The prior art fails to even remotely disclose or suggest two discrete and separate administration forms as required by the present claims.

In the in-person interview held on November 22, 2005 between Applicant's representative(s), Supervisory Examiner T. K. Page and myself, suggestions were made to distinguish over the cited art of record by specifically incorporating the limitations of instant claim 43, into independent claim 21, wherein instant claim 43 recites a 'sustained release coating film comprising a water-insoluble and physiologically tolerable plastic membrane having low swelling power in water and in which small soluble particles are embedded'. In Applicant's

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response filed 11/28/05, Applicant(s), through their attorney, have amended claim 21 by incorporating the limitations of claim 43 (to include the presence of small particles in the sustained release coating film), have cancelled claim 43 and have adopted the Examiner's suggestions to distinguish the instant administration form over the cited art of record. Based on the lack of teachings by the prior art to provide for an oral fixed combination administration form, provided in a capsule in two discrete and separate dosage administration forms, separately bearing either an enteric coating or a sustained-release coating, whereby the sustained release coating film is a water-insoluble and physiologically tolerable plastic membrane having low swelling power in water and in which small soluble particles are embedded, the instant invention is rendered non-obvious and patentable over the cited art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh
Patent Examiner



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February 14, 2006

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